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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/667,187 | 09/17/2003 | Michael J. Munchhof | PC25292A | 9326 |
| 28523 | 7590 | 03/10/2005 | EXAMINER | |
| PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340 | | | | OWENS, AMELIA A |
| ART UNIT | | PAPER NUMBER | | |
| | | 1625 | | |

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/667,187 | MUNCHHOF ET AL. |
| | Examiner | Art Unit |
| | Amelia A. Owens | 1625 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 December 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,11 and 12 is/are rejected.
 7) Claim(s) 2-10 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____

DETAILED ACTION

Claim 13 has been canceled. Claims 1-12 are pending.

Information Disclosure Statement

The examiner has considered the IDS.

Election

Applicants election in paper dated 6-21-2004 is noted. It is not seen where species containing the selected R1 group are exemplified. MPEP 809.02(a)(C). Applicants must elect a single 'disclosed' species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The transitional term 'comprising', which is synonymous with 'including', 'containing', or 'characterized by', is inclusive or open-ended and does not exclude additional unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) ('comprising' leaves 'the claim open for the inclusion of unspecified ingredients even in major amounts'). See MPEP 211.03.

Claim 11 is self conflicting because the claim is drawn to pharmaceutical compositions without a dosage limitation. Please note that a pharmaceutical composition by definition cannot

be either ineffective or toxic. Therefore a pharmaceutical composition without any dosage is self conflicting. It is recommended that the term 'therapeutically effective amount' be incorporated into the claim.

For claim 1 the language 'saturated, unsaturated, or aromatic C3-C20 mono, bi-or polycyclic ring....heteroatom selected from the group consisting of N, O and S' is confusing. It is unclear 'what' structure such terms are defining. What structure is specifically being claimed?

Claims 1 and 12 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The nature of the invention: The nature of the invention is the method of treating TGF-related disease state....from the TGF-related disease state selected from the group consisting of cancer.... See claim 12.

The state of the prior art and predictability: “Cancer” encompasses the scope of all forms of neoplasm which may metastasize and cause death. Therefore method of treating cancer including those have yet to be discovered, is a reach through claim. Reach through claim fail to meet patentability requirement for lacking operability since method of treating all cancer known to man, and to be discovered by may is wholly inoperable. Further, cancer treatment has been known to be compound and disease specific, that is a particular compound or class of compound can be useful in treating a particular type/class of cancer. Assay tests such as those in the specification are indicate the compound qualifies for further testing but does not offer therapeutic value.

The amount of guidance and working examples: The specification prepares several compounds according to the invention. The assay tests is considered as a screen for treating cancer and can not be extrapolated without multiple cancer type to the generic scope as sought by the claims. The specification lacks any real world target, steps, site of administration, dosage as to provide the public how to operate the claimed method.

For claim 1, Applicants remarks regarding the term ‘prodrug’ are noted and are not found to be persuasive. A copy of the Burger reference has not been provided. Further, the Ettmayer et al and Webster et al documents are both written after applicants filing date. This raises the question of whether applicants were in possession of prodrugs of their compound at the time the invention was filed.

It is noted that the term ‘prodrug’ encompasses an enormous field of pharmaceutical derivatization. In absence of any definition or specific description and enablement, the skilled

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artisan was not offered any guidelines as to which functional group can be derivatized with what material.

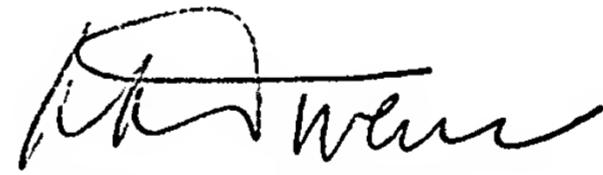
This rejection can be overcome by deleting the claims.

Claims 2-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amelia A. Owens whose telephone number is 571-272-0690. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Amelia A. Owens
Primary Examiner
Art Unit 1625